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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,979	09/04/2001	Kazuyuki Hamada	0230-0163P	6058

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EXAMINER

KUBELIK, ANNE R

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 10/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/856,979	Applicant(s) HAMADA ET AL.	
	Examiner Anne R. Kubelik	Art Unit 1638	

-- Th. MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>9</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 11-18 are pending.
2. The drawings are objected to for the reasons indicated on the accompanying form PTO 948. Corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance. See 37 CFR 1.85(a) and MPEP 608.02(b).
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Amendment

4. The rejection of claims 11-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over each of Michiels et al (WO 92/13956) and Michiels et al (1997, US Patent 5,639,948) is withdrawn in favor of a 102 rejection over those references, given Applicant's amendment of the claims.

Claim Objections

5. Claims 12-13 and 15-16 are objected to because of the following informalities:
Claims 12 and 13 have an improper article before "nucleotide" in line 2.
In claims 15 and 16, line 3, "less" should be replaced with --fewer--.

Claim Rejections - 35 USC § 112

6. Claims 11-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for promoters of SEQ ID NOs:6 and 7, methods of using them to make male-sterile plants, and plants so obtained, does not reasonably provide enablement for promoters that are portions of SEQ ID NO:6 or modified versions of SEQ ID NO:7, methods of using them to make male-sterile plants, and plants so obtained. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The rejection is repeated for the reasons of record as set forth in the Office action mailed 15 January 2003, as applied to claims 1-6 and 7-10. Applicant's arguments filed 15 July 2003 have been fully considered but they are not persuasive.

Applicant urges that it would not cause a skilled artisan undue experimentation to use a part or a modification of SEQ ID NO:6 or 7 and that these promoters are completely distinguishable from those cited in the references.

This is not found persuasive. Applicant does not point out why they think that these promoters are distinguishable from the cited references. The references teach that mutation of promoters is unpredictable, as is isolation of functional parts of promoters. For example, Chen et al (2000, Sex. Plant Reprod. 13:85-94) teach that two promoters with similar expression patterns have major differences in the expression elements required for expression in various flower parts (pg 92, right column, last two paragraphs), and Kim et al (1994, Plant Mol. Biol. 24:105-117) teach even a very small region may be critical for activity, and the criticality of a particular region must be determined empirically (Tables 1-4, Abstract, Fig. 1-2).

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Applicant points out that one of the important features of the instant invention is that the first promoter comprises a part of SEQ ID No:6 and that thus one of skill in the art can practice the invention within the scope of the claims (response pg 7).

This is not found persuasive. The claims are drawn to a construct comprising a part of SEQ ID NO:6 and methods of its use. A part of SEQ ID NO:6, which is 1695 nucleotides long, can be as small as 1 base and as large as 1695 bases long and can comprise any bases on either side of it. However, the only “part” of SEQ ID NO:6 that Applicant teaches is functional as a promoter is SEQ ID NO:7, which is 365 bases long. The specification does not teach other fragments within the full scope of the claims. Constructing those other fragments would require undue experimentation. There are 1695! different possible fragments of SEQ ID NO:6.

Making all possible single nucleotide substitutions in SEQ ID NO:6 would require making and analyzing 4^{1695} nucleic acids; these nucleic acids would have 99.9% identity to SEQ ID NO:6. Making all possible single nucleotide substitutions in SEQ ID NO:7 would require making and analyzing 4^{365} nucleic acids; these nucleic acids would have 99.7% identity to SEQ ID NO:7. Because nucleic acids with 90% identity to SEQ ID NO:6 would have 16 nucleotide substitutions, many more than 4^{1695} nucleic acids would need to be made and analyzed. Similarly more than would need to be made to make nucleic acid with 90% identity to SEQ ID NO:7. Given the claim breadth, unpredictability, and lack of guidance, undue experimentation would have been required by one skilled in the art to develop and evaluate promoters with 90% identity to SEQ ID NO:6 or 7 or with 5 or 10 nucleotide substitutions or deletions of SEQ ID NO:6 or 7.

Applicant urges that claims 12 and 13 are drawn to promoters with 90% homology to SEQ ID No:6 or 7, which is supported by the specification on pg 6-7, and that claims 15-16 are

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drawn to promoters with fewer than 10 bases of modification, as disclosed on pg 7 of the specification (response pg 7).

This is not found persuasive because mention of “90% homology” or a number of bases to modify or delete does not teach WHICH bases to modify or delete.

7. Claims 11-18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is repeated for the reasons of record as set forth in the Office action mailed 15 January 2003, as applied to claims 1-5 and 7-10. Applicant’s arguments filed 15 July 2003 have been fully considered but they are not persuasive.

Applicant urges that a promoter fragment is disclosed as SEQ ID NO:4 and that one of the important features of the instant invention is that the first promoter comprises a part of SEQ ID NO:6. Thus, Applicant urges that one of skill in the art can practice the invention as claimed (response pg 8).

This is not found persuasive. SEQ ID NO:4 comprises the E1 promoter ligated to the barnase gene (see specification, pg 13, lines 3-5), and not a fragment of SEQ ID NO:6. Furthermore, SEQ ID NO:7, which is a fragment of SEQ ID NO:6 is the only such fragment of SEQ ID NO:6. One fragment does not describe a broad genus of fragments.

A part of SEQ ID NO:6, which is 1695 nucleotides long, can be as small as 1 base and as large as 1695 bases long and can comprise any bases on either side of it. However, the only “part” of SEQ ID NO:6 that Applicant teaches is functional as a promoter is SEQ ID NO:7, which is 365 bases long. There are 1695! different possible fragments of SEQ ID NO:6. The

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specification does not describe fragments of SEQ ID NO:6 that function as promoters within the full scope of the claims.

See *Univ. of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed. Cir. 1997):

pg 1406:

... A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus.

See *In re Shokal*, 113 USPQ 283, (CCPA 1957) at pg 285

It appears to be well settled that a single species can rarely, if ever, afford sufficient support for a generic claim. In *re Soll*, 25 C.C.P.A. (Patents) 1309, 97 F.2d 623, 38 USPQ 189; In *re Wahlforss et al.*, 28 C.C.P.A. (Patents) 867, 117 F.2d 270, 48 USPQ 397. The decisions do not however fix any definite number of species which will establish completion of a generic invention and it seems evident therefrom that such number will vary, depending on the circumstances of particular cases. Thus, in the case of small genus such as the halogens, consisting of four species, a reduction to practice of three, or perhaps even two, might serve to complete the generic invention, while in the case of a genus comprising hundreds of species, a considerably larger number of reductions to practice would probably be necessary. ...

We are of the opinion that a genus containing such a large number of species cannot properly be identified by the mere recitation or reduction to practice of four or five of them. As was pointed out by the examiner, four species might be held to support a genus, if such genus is disclosed in clear language; but where those species must be relied on not only to illustrate the genus but to define what it is, the situation is otherwise.

8. Claims 1-6, 8 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections. The rejection is modified from the rejection set forth in the Office action mailed 15 January 2003, as applied to claims 1-6, 8 and 10. Applicant's arguments filed 15 July 2003 have been fully considered but they are not persuasive.

Claims 14-16 are indefinite in their recitation of "the sequence obtained by modifying ... nucleotides". It is unclear which nucleotides are substituted, deleted or added and what the sequence of the claimed promoter is. Thus, the metes and bounds of the claim are unclear.

Applicant urges that one of skill in the art can predict and produce various substitutions and/or deletions in the sequence without undue experimentation (response pg 9).

This is not found persuasive. Applicant's arguments are drawn to a 112, 1st, rejection, not a 112, 2nd rejection.

The following rejections are new, due to amendment:

Claims 12 -13 are indefinite in their rejection of "homology". It is unclear if "identity" is intended or if "homology" means something else.

Claims 14-15 lack antecedent basis for the limitation "the same".

Claim Rejections - 35 USC § 102

9. Claims 11-18 are rejected under 35 U.S.C. 102(b) as being anticipated by each of Michiels et al (WO 92/13956) and Michiels et al (1997, US Patent 5,639,948). The rejection is repeated for the reasons of record as set forth in the Office action mailed 15 January 2003, as applied to claims 1-5 and 7-10. Applicant's arguments filed 15 July 2003 have been fully considered but they are not persuasive.

Applicant urges that pg 4, lines 7-22 of the specification states that effect of the upper part of the E1 promoter on the expression of the barnase gene would have been compromised by the intervention of a 10 kb transposon, resulting in decreased expression of the barnase gene.

This is not found persuasive. The relevance of this is unclear, as Michiels et al teach plasmid vectors that have a 1690 bp part of the E1 promoter operably linked to the barnase gene and an anther-specific promoter operably linked to the Barstar gene, a method of using them to produce male-sterile plants, and rice, corn and tobacco plants so obtained (pg 20-33 of WO 92/13956 and column 9, line 46, to column 20, line 30 of '948).

Applicant urges that Michiels et al, on the other hand, simply disclose that the minimum another specification region of the E1 promoter exists in about 300-500 bp upstream of the starting codon (response pg 10-11).

This is not found persuasive, given that Micheils et al teaches constructs with a part of the E1 promoter. This promoter comprises SEQ ID NO:7.

Applicant urges that Michiels et al do not even suggest the production of a male-sterile plant free from morphological abnormality, which is obtained by the instant invention (response pg 11).

This is not found persuasive. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., production of a male-sterile plant free from morphological abnormality) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

10. Claims 11 and 17-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Mariani et al (1998, US Patent 5,792,929). The rejection is repeated for the reasons of record as set forth in the Office action mailed 15 January 2003, as applied to claims 1-5 and 7-10. Applicant's arguments filed 15 July 2003 have been fully considered but they are not persuasive.

Applicant urges that Mariani et al do not even suggest the production of a male-sterile plant free from morphological abnormality, which is obtained by the instant invention (response pg 11-12).

This is not found persuasive. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which

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applicant relies (i.e., production of a male-sterile plant free from morphological abnormality) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (703) 308-5059. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service at (703) 308-0198.

Anne R. Kubelik, Ph.D.
October 2, 2003



AMY J. NELSON, PH.D.
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